

Proposed Decision Memo for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-00429N)

Decision Summary

CMS proposes coverage for Transcutaneous Electrical Nerve Stimulation (TENS) for chronic low back pain (CLBP) only when all of the following conditions are met.

A. For the purposes of this decision CLBP is defined as:

- a. an episode of low back pain that has persisted for three months or longer; and
- b. is not the result of certain well-defined diseases that may contribute to low back pain but which are not primarily low back syndromes.

For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom. Certain systemic diseases, e.g. rheumatoid arthritis, multiple sclerosis etc, manifest many debilitating symptoms of which low back pain is not the primary focus. We believe that the appropriate management of these types of diseases is guided by a systematic strategy aimed at the underlying causes. While TENS may infrequently be used adjunctively in managing the symptoms of these diseases, it is clearly not the primary therapeutic approach.

B. The patient is enrolled in a prospective clinical study that addresses one or more aspects of the following questions in a randomized, controlled design using validated and reliable instruments. This can include randomized crossover designs.

- 1. Does the use of TENS provide a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
- 2. Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?
- 3. Does the use of TENS provide a clinically meaningful reduction in other medical treatments or services used in the medical management of CLBP?

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- a. The principal purpose of the clinical study is to test whether TENS potentially improves the participants’ health outcomes.
- b. The clinical study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- c. The clinical study does not unjustifiably duplicate existing studies.
- d. The study design is appropriate to answer the research question being asked in the study.
- e. The clinical study is sponsored by an organization or individual capable of successfully executing the proposed study.
- f. The clinical study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46.
- g. All aspects of the clinical study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- h. The clinical study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
- i. The clinical study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals.
- j. The clinical study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.

- k. The clinical study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors

(http://www. icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
- l. The clinical study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- m. The clinical study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

We are requesting public comments to this proposed decision pursuant to section 1862(l) of the Social Security Act (the Act). After consideration of the public comments and any additional evidence, we will issue a final determination responding to the public comments consistent with §1862(l)(3) of the Act.

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Proposed Decision Memo

TO: Administrative File: (CAG #00429N)

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SUBJECT: Proposed Decision Memorandum for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-00429N)
DATE: March 13, 2012

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II. Background

Low back pain (LBP) is a widespread complaint in the United States. It is the fifth most common complaint for which professional health care advice is sought [Rathmell 2008; Chou 2010]. Approximately 75 - 80% of individuals in the United States will experience an episode of LBP in their lifetime; there is a 5% annual incidence of the condition. [Weinstein 2005] It is estimated that greater than 17 million elderly individuals experience at least one episode of LBP in a year in the U.S. [Morone 2009].

The causes of LBP can be difficult to determine. In a minority of patients, a medical history, physical examination, and appropriate laboratory/imaging studies can identify causes such as cancer, infection, compression fractures and inflammatory arthropathies such as ankylosing spondylitis. However, there is no well-defined etiology of the pain in approximately 85% of individuals who present with LBP [Negrini 2010].

For most people, LBP is a short-lived condition whether or not treatment is provided, lasting less than 12 weeks for 80-90% of those who experience it. However, a small but significant proportion of individuals, approximately 10 – 20%, will experience a continuation of LBP with disabling symptoms [Rathmell 2008; Chou 2010].

Many authors define persistent LBP lasting greater than or equal to 12 weeks or 3 months to be chronic [Khadilkar 2005; Machado 2008; Poitras 2007; van Middelkoop 2011]. We also, for the purposes of this decision memorandum, define CLBP as LBP that has persisted at least three months. Proposed treatment regimens for CLBP include a range of interventions including physical therapy, behavioral therapy, TENS, drug therapy, and surgery. Examples of physical therapy treatments include exercise therapy, traction, and body biomechanics education. These treatments are meant to reduce pain, inflammation, and muscle spasm, as well as increase strength and range of motion, and improve functional status.

TENS involves the delivery of electric current to the skin through surface electrodes, primarily for the intended purpose of pain relief. TENS has been used as a therapy for musculoskeletal pain in many anatomic sites of the body; it has also been used to treat post-surgical pain, labor pain, primary dysmenorrhea, as well as the pain associated with a host of other medical conditions.

TENS units are usually small, portable battery operated devices that deliver electrical current to the skin through electrodes. They are usually administered by a therapist in a clinical setting, and then self-administered by the patient, once adequately instructed. Usually, several skilled therapy sessions are required to establish the optimal stimulation settings and sites of electrode placement for a patient.

In clinical practice, the electrical characteristics of TENS units are varied among the devices used and the clinicians who apply them [Knight 2008]. Two examples of commonly used approaches are a frequency greater than 50 Hz (i.e., conventional or traditional TENS) or a frequency of 1-10 Hz (low frequency or acupuncture-like TENS) [Sluka 2009]. Conventional TENS is usually perceived by a patient as a tingling sensation, while low frequency or acupuncture-like TENS is experienced as a burning, needling sensation [Knight 2008]. TENS devices can also be configured to deliver different types of output patterns for individual patients, including those that produce constant pulses, and those that provide repetitive trains or bursts of electrical pulses delivered in a limited time period, followed by a specified period of no current flow. Moreover, a TENS device may also be configured to produce a modulated output, so that one or several of the parameters of the electrical stimulation are cyclically changed during a single application of treatment [Sluka 2009].

A variant of TENS, also included in this review, is interferential current (IFC) therapy. This form of treatment applies two separate medium frequency (2000 – 4000 Hz) sinusoidal currents to the skin simultaneously. These two currents can then be superimposed upon each other, so that the resultant current is different from either of the initiating currents. The rationale behind the application of dual electric currents is based on the fact that the impedance (or resistance) of skin and subcutaneous tissue is inversely proportional to the frequency of stimulation. Therefore, there is less resistance to current at 3000 Hz than there is at 300 Hz. Proponents of IFC therapy state that the combined currents will pass more easily through the skin and reach deeper levels of tissues producing stronger physiologic effects, while at the same time causing less discomfort than would be required by other forms of TENS [Knight 2008; Sluka 2009].

There are several theories that have been hypothesized to support the clinical use of TENS for pain relief. Originally, the Melzack and Wall gate theory of pain was considered as the foundation of the mechanism of action for TENS. In this theory, a “gate” in the dorsal horn of the spinal cord has the capacity to inhibit transmission of nociceptive stimulation to the ascending tracts of the nervous system. By using TENS to activate the large diameter afferent nerves of the peripheral nervous system, it was believed that these devices could block the noxious painful sensations that were being felt by the patient [Walsh 2010]. However, as more research has accumulated, investigators now believe that TENS may produce pain relief by activating the supraspinal nervous system as well as the afferent nerves that affect the spine. These effects are proposed to occur at least in part, due to the modulation of the body’s endogenous chemicals (e.g., endorphins, glutamate, etc.) that affect the perception of pain [DeSantana 2008; Sluka 2009]. Some also claim that the use of TENS causes a local dilatation of blood vessels in injured tissues [Noble 2000], that might mitigate nociceptive sensations.

For purposes of research conducted to determine the effectiveness of TENS, pain measurement tools usually incorporate the use of scales and questionnaires. Using these measures, improvement or worsening of pain symptomatology can be tracked over time. Among the tools commonly used to quantify pain are:

- a. Number scales – Used to measure pain intensity, these scales consist of a range of numbers (e.g., 0 – 100) with descriptors providing general correlative indications (e.g., 0 = no pain; 100 = maximal pain). Subjects are asked to identify the number that best describes their pain.
- b. Visual analog scale (VAS) – A VAS is an unnumbered line, frequently 100 mm in length, with contrasting descriptors at either end. The descriptors could be for example, no pain/worst pain, sharp/dull, etc. The patient is asked to make a vertical mark at the point along the continuum that best represents their pain level. The investigator measures the distance of the patient’s marking from the left side of the line; this measure denotes the pain score [Knight 2008].

Investigators have also attempted to measure the effects of pain reduction or worsening through the use of questionnaires that gather patient perceptions of their activity and disability status. Examples of such outcomes instruments include:

- a. Oswestry disability index (ODI) – The ODI is used to determine those activities of daily living (e.g., standing, walking, lifting, sitting, and personal care) that are disturbed by the presence of low back pain. Each item is answered on the basis of pain being experienced “today.” The ODI can be self-administered [Ostelo 2005].
- b. Roland Morris Disability Questionnaire (RDQ) – The RDQ is a condition-specific health status measurement tool created to assess physical function in individuals with low back pain. Patients select from 24 items that describe their current activities/limitations (e.g., walking, standing, bending/kneeling, sleeping, etc.) due to their back pain “today.” The RDQ can be self-administered [Ostelo 2005].
- c. McGill Pain Questionnaire – This questionnaire is a self-administered tool. Patients draw the location of their pain on a body diagram and use the listed pain descriptors and pain scales to express the characteristics and magnitude of their discomfort [Knight 2008].

Additionally, indirect measures such as strength, range of motion and physical functioning may be used to determine the effectiveness of pain interventions.

III. History of Medicare Coverage

Current National Coverage Determinations (NCDs)

The National Coverage Determinations Manual has four NCDs addressing several uses of TENS in various settings including home use and supervised use outside the home. Below we have listed the NCDs that will be affected by this proposed decision.

- Assessing Patient’s Suitability for Electrical Nerve Stimulation Therapy (160.7.1)
- Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13)
- Transcutaneous Electrical Nerve Stimulators (TENS) (280.13)

Assessing Patient’s Suitability for Electrical Nerve Stimulation Therapy (160.7.1)

A. Transcutaneous Electrical Nerve Stimulation (TENS)

This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of 1 month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain.

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS from a supplier during the trial period rather than supplying it himself/herself, program payment may be made for rental of the TENS as well as for the services of the physician or physical therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.....

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §160.7 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See §280.13 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13)

Indications and Limitations of Coverage

A form-fitting conductive garment (and medically necessary related supplies) may be covered under the program only when:

- 1. It has received permission or approval for marketing by the Food and Drug Administration;
- 2. It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and
- 3. One of the medical indications outlined below is met:
 - o The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;
 - o The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;
 - o The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;
 - o The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or
 - o The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS device during the trial period specified in §160.3 unless:

- 1. The patient has a documented skin problem prior to the start of the trial period; and
- 2. The carrier's medical consultants are satisfied that use of such an item is medically necessary for the patient.

Transcutaneous Electrical Nerve Stimulators (TENS) (280.13)

TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic).

Indications and Limitations of Coverage
Payment for TENS may be made under the durable medical equipment benefit.

Current Request

CMS generated this request internally. We limited our review to CLBP as defined above. We specifically excluded certain well defined diseases that may contribute to low back pain but which are not primarily low back syndromes. For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom. Certain systemic diseases, e.g. rheumatoid arthritis, multiple sclerosis etc, manifest many debilitating symptoms of which low back pain is not the primary focus. We believe that the appropriate management of these types of diseases is guided by a systematic strategy aimed at the underlying causes. While TENS may infrequently be used adjunctively in managing the symptoms of these diseases, it is clearly not the primary therapeutic approach.

Benefit Category

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage, §1812 (Scope of Part A); §1832 (Scope of Part B) §1861(s) (Definition of Medical and Other Health Services). Transcutaneous electrical nerve stimulation is durable medical equipment (DME), as referenced in §1861(s)(6) of the Act. This may not be an exhaustive list of all benefit categories for TENS.

IV. Timeline of Recent Activities

September 13, 2011 CMS posts a tracking sheet and opens a National Coverage Determination (NCD). The initial 30-day public comment period begins.

October 13, 2011 Initial public comment period ended. CMS received a total of 359 comments.

V. FDA Status

The FDA has cleared many TENS devices for pain relief. A manufacturer who intends to market a device of this generic type must conform to the general controls of the Federal Food, Drug, and Cosmetic Act, including the premarket notification requirements described in 21 CFR 807 Subpart E and obtain a substantial equivalence determination from FDA prior to marketing the device (section 513(a)(1)(B) of the Act; 21 USC 360c(a)(1)(B)).

VI. General Methodological Principles

In general, when making NCDs under §1862(a)(1)(A), CMS evaluates relevant clinical evidence to determine whether or not the evidence supports a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or improves the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for Medicare beneficiaries. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary under §1862(a)(1)(A) of the Act.

A detailed account of the methodological principles of study design that are used to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, the blinding of readers of the index test, and reference test results.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination.

VII. Evidence

A. Introduction

This section provides a summary of the evidence we considered during our review. The evidence reviewed to date in this NCD includes the published medical literature on pertinent clinical trials of TENS for CLBP.

B. Discussion of Evidence Reviewed

1. Questions

In order to determine if TENS improves the health outcomes of Medicare beneficiaries with CLBP, we pose the following questions:

1. Does the use of TENS produce a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
2. Does the use of TENS produce a clinically meaningful improvement in function in Medicare beneficiaries with CLBP?
3. Does the use of TENS produce a clinically meaningful, improvement in any other health outcome in Medicare beneficiaries with CLBP?

If the answer to any of the questions above is affirmative, is the evidence sufficient to confidently identify the patient or device characteristics that predict improved health outcomes?

2. External Technology Assessment:

An external technology assessment was not commissioned for this review.

3. Internal Technology Assessment

Systematic reviews are based on a comprehensive search of published studies to answer a clearly defined and specific set of clinical questions. A well-defined strategy or protocol (established before the results of the individual studies are known) guides this literature search. Thus, the process of identifying studies for potential inclusion and sources for finding such articles is explicitly documented at the start of the review. Finally, systematic reviews provide a detailed assessment of the studies included.

Literature search methods

We searched the PUBMED and EMBASE databases, the Cochrane Library, and the National Guidelines Clearinghouse up to August 2011. Search terms included ‘TENS for chronic low back pain’ and ‘transcutaneous electrical nerve stimulation for chronic low back pain.’ We identified those studies with and without randomized control trial (RCT) design, meta-analyses and systematic reviews. Of the references found, we read through the abstracts and titles to find those that met the criteria below. We also reviewed references submitted to us by commenters and performed a hand search of bibliographies to identify other pertinent articles.

For the purpose of this analysis, we reviewed clinical trials with the following inclusion criteria:

- Adults with chronic low back pain (with or without leg pain) present for 3 months or greater
- Studies with ten or more patients
- Trials with well-defined comparators
- Studies where participants used TENS over a period of at least 4 weeks
- All models, frequencies, and wave patterns of TENS applied superficially to the skin

Studies including data on individuals who experienced less than 3 months of pain or reported outcomes after less than 4 weeks of TENS treatment were included if subgroup analyses were performed meeting the criteria as above.

We excluded studies that examined chronic low back pain in individuals with pain related to malignancy, neurodegenerative diseases (e.g. multiple sclerosis), and well-defined rheumatic disorders (except for osteoarthritis).

Systematic reviews and meta-analyses that had as their main objective, either in part or in whole, a comparison of TENS versus sham TENS and/or other therapies for patients with chronic low back pain from the year 2005 forward were also included in our review. Those that discussed the use of TENS in the treatment of combined musculoskeletal conditions or in combined acute/chronic LBP were excluded if subgroup analyses were not performed within our parameters of interest.

Based on the criteria noted above, CMS has found a limited number of studies (see Table 2 for articles excluded from review). The pertinent rationale for our inclusion/exclusion criteria is twofold:

(1) CMS has chosen to remove from consideration of this decision the literature that studies LBP associated with neurodegenerative (e.g. multiple sclerosis) disease, malignancy, or well-defined rheumatic disorders (except osteoarthritis). It is possible that the mechanisms of pain as well as pain relief in these conditions may significantly differ from those of the more common causes of CLBP found in our patient population. (2) Furthermore, while LBP complaints are common, studies indicate that about 80% of lower back pain resolves in approximately 6 weeks, leaving 10-20% of those individuals experiencing this complaint to have discomfort that is more long-lasting [Rathmell 2008 and Chou 2010]. CMS defines chronic low back pain (CLBP), for the purpose of this NCD, as pain that persists for 3 months or longer. Using this definition, we believe that individuals with CLBP can experience pain for years or even for a lifetime. Therefore, any therapeutic measure taken to diminish or relieve the pain must be able to be safely applied over the long term, and should ideally exhibit an enduring clinical benefit.

Systematic Reviews and Meta-analyses

Dubinsky R, Miyasaki J. Assessment: Efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2010;74:173-176.

This systematic review summarizes the evidence on the efficacy of TENS in the treatment of pain associated with neurologic disorders, including CLBP. The authors searched MEDLINE and the Cochrane Library for clinical trials of more than ten patients that compared TENS to placebo or to another therapy to treat low back pain of differing etiologies, including multiple sclerosis. The authors noted that there were varied definitions among the included clinical trials for meaningful reduction in pain. Five studies were evaluated.

The review concluded that there was conflicting evidence for the use of TENS in the treatment of CLBP and that TENS should be deemed ineffective for this purpose.

Khadilkar A, Milne S, ,Brosseau L, Robinson V, Saginur M, Shea B, Tugwell P, Wells G. Transcutaneous electrical nerve stimulation (TENS) for chronic low-back pain. *The Cochrane Database of Systematic Reviews*, 2005, Issue 3. Art. No.:CD003008. DOI: 10. 1002/14651858. CD003008. pub2.

The main objective of this systematic review was to determine the effectiveness of transcutaneous electrical nerve stimulation in the treatment of chronic low back pain. A secondary goal was to determine the most effective parameters to administer TENS. These parameters could include stimulation factors, sites of application, application techniques and duration of treatment. The authors searched MEDLINE from 1966 to April 2005; EMBASE, and the Physiotherapy Evidence Database (PEDro) up to April 2005; and the Cochrane Controlled Trials Register, Issue 1, 2005. The authors included randomized controlled trials of outpatients 18 years old and above, with a diagnosis of chronic (greater than 12 weeks), mechanical low back pain. Patients with signs and symptoms of sciatic pain or a previous history of back surgery were not excluded. However, patients with malignancy, infection, inflammatory disorder or neurological syndromes were specifically excluded. All standard models of TENS were included and sham TENS was considered an acceptable placebo. Studies in which patients were provided TENS treatment percutaneously with acupuncture needles were excluded.

Only 2 articles met the inclusion criteria of this review. The authors concluded that the evidence provided inconsistent support for the use of TENS as an isolated treatment modality in the treatment of CLBP.

Machado L, Kamper S, Herbert R, Maher C, McAuley J. Analgesic effects of treatments for non-specific low back pain: a meta-analysis of placebo-controlled randomized trials. *Rheumatology*. 2009;48:520-527.

The goal of this article was to perform a systematic review and meta-analysis of placebo controlled randomized trials investigating the effects of treatment upon nonspecific low back pain (NSLBP). The authors searched MEDLINE, EMBASE, CINAHL, PyschInfor, and the Cochrane Central Register of Controlled Trials from the earliest record to November 2006. The authors included randomized controlled trials comparing treatments for NSLBP against placebo. Only trials with continuous measures of pain were accepted for review. Studies in which participants demonstrated radicular syndrome, cauda equina syndrome, infection, neoplasm, fracture, inflammatory disease, pregnancy or spinal surgery in the past 12 months were excluded. Also excluded were studies of primary prevention as were trials in which the placebo was a contemporary treatment (e.g. an educational booklet). The authors used the definitions of the American College of Physicians and the American Pain Society to evaluate the magnitude of treatment effects: large > 20 points; moderate 10-20 points; and small < 10 points). A secondary analysis was performed to evaluate the efficacy of treatments in individuals with specific duration of symptoms. In this analysis, the authors combined those trials in which patients experienced pain for greater than 6 weeks, into their definition of CLBP.

Two trials, with a total of 57 patients, were found investigating the use of TENS for CLBP as defined by the authors. The authors concluded that there was a moderate effect favoring analgesic efficacy with TENS. However, they also noted that the confidence intervals around these estimates of pain relief were not narrow enough to rule out small effects.

McIntosh G, Hall H. Low back pain (chronic). *Clinical Evidence*. 2008;10:1116.

This is a systematic review that studied the effects of various treatments for chronic low back pain, including non-drug treatments. The authors searched for English language journals of RCTs or systematic reviews that contained trials that were at least single blinded (unless impossible) and included more than 20 subjects (with at least 80% follow up). The search included BMJ Clinical Evidence in May 2007, MEDLINE (1966-May 2007), EMBASE (1980-May 2007), Psychlit (1984-May 2007), The Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Clinical Trials 2007, Issue 2 and several websites(NHS Centre for Reviews and Dissemination, Health Technology Assessment, Turning Research into Practice, and NICE). The authors defined chronic low back pain as "pain, muscle tension, or stiffness localized below the costal margin and above the inferior gluteal folds, with or without leg pain (sciatica)," of at least twelve weeks duration. They included studies of people with chronic low back pain with no radiation of discomfort, or studies that included subjects both with and without radiation, if the proportion of people with radiation was less than 50 percent. They excluded studies in which the participants exhibited chronic low back pain with symptoms or signs that suggest a specific underlying condition (e.g. infection, tumor, osteoporosis, rheumatoid arthritis, fracture or inflammation), and studies where the subjects manifested only sciatica and/or pain due to herniated discs.

Two systematic reviews and one RCT were included in the review. The authors concluded that the decision to use TENS as an isolated treatment for CLBP is poorly defined by the evidence.

Poitras S, Brosseau L. Evidence-informed management of chronic low back pain with transcutaneous electrical nerve stimulation, interferential current, electrical muscle stimulation, ultrasound, and thermotherapy. *The Spine Journal*. 2008;8:226-233.

This review evaluates the efficacy of TENS and other modalities for the treatment of nonspecific or rheumatic chronic low back pain that has lasted longer than 12 weeks. The authors searched for French and English RCTs and controlled clinical trials in MEDLINE, EMBASE, Current Contents, CINAHL, and the Cochrane Controlled Trials Register up to August 2006. They also searched the registries of the Cochrane Field of Rehabilitation and Related Therapies and the Cochrane Musculoskeletal Group and the Physiotherapy Evidence Database. Generally, comparisons of two active treatments were excluded as were trials where the patient acted as his/her own control. Trials with subjects that received the placebo, were untreated, or received routine conventional therapeutic approaches were accepted as controls. If concurrent therapies were provided to both investigative and control groups, these trials were also accepted. To a limited extent, cross over trials were included, but only the data prior to the first crossing was analyzed. Studies with differing electrical parameters and treatment frequencies were accepted.

In summary, the authors concluded that most of the TENS studies were of poor methodological quality and that variations in TENS parameters and treatment session characteristics made comparisons difficult. The authors also concluded that TENS may have an impact on the reduction of pain in the immediate and short term, but does not appear to have an impact on perceived disability or long term pain.

van Middelkoop M. et. al. A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. *European Spine Journal*. 2011;20:19-39.

The objective of this systematic review was to determine the effectiveness of various physical and rehabilitation interventions for CLBP. All standard modes of TENS were among the interventions studied. In the investigations included for review, TENS was compared against sham treatment, percutaneous electrical nerve stimulation/acupuncture, and other active treatments. Also conventional TENS was compared to biphasic new wave TENS. The authors searched the Cochrane reviews, MEDLINE, EMBASE, CINAHL, and PEDro up to December 2008 and included articles in English, Dutch, and German. They included RCTs of adults over 18 years of age, with non-specific chronic low back pain that persisted for 12 or more weeks and that evaluated at least one clinically relevant outcome measure (pain, functional status, perceived recovery, or return to work). The authors excluded RCTs where subjects demonstrated specific low back pain due to conditions such as vertebral spinal stenosis, ankylosing spondylitis, scoliosis, and coccydynia.

Comparing TENS to sham treatment, the authors concluded that no statistically significant difference on post-treatment pain intensity and disability was found. Further they noted that percutaneous electrical nerve stimulation/acupuncture is more effective than TENS for post treatment and short term pain relief. Between TENS and active treatments, they noted that studies demonstrated there was no statistically significant difference in pain intensity. Finally, one study found no statistically significant differences in the comparison of conventional TENS with biphasic new wave TENS in terms of pain intensity and disability. The authors noted that most of the evidence reviewed was of low quality or was at high risk of bias.

Single Study Investigations

We found six single study investigations that fit our inclusion criteria. Five were randomized controlled trials (RCTs) and one used a sequential allocation design. The details of these trials are presented in Table 1 and summarized below.

Deyo R, Walsh N, Martin D, Schoenfeld L, Ramamurthy S. A Controlled Trial of Transcutaneous Electrical Nerve Stimulation (TENS) and Exercise for Chronic Low Back Pain. *New England Journal of Medicine*. 1990;322(23):1627-1634.

The purpose of this study was to examine the efficacy of TENS and stretching exercises alone and in combination for the relief of low back pain. One hundred forty five subjects with CLBP (ages 18-70 years) were randomly assigned to one of 4 groups, including the use of TENS alone and sham TENS. Outcome measures included those related to pain ratings, functional status, physical performance and the use of medical services. Outcomes were recorded after two and four weeks of home therapy and then again two months after the TENS had been discontinued. The authors concluded that for patients with CLBP, treatment with TENS was no more effective than treatment with a placebo and that TENS adds no apparent benefit to exercise alone.

Itoh K, Itoh S, Katsumi Y, Kitakoji H. A pilot study on using acupuncture and transcutaneous electrical nerve stimulation to treat chronic non-specific low back pain. *Complementary Therapies in Clinical Practice*. 2009;15:22-25.

The goal of this study was to determine whether acupuncture, TENS, or a combination of acupuncture and TENS was more effective for the treatment of chronic, nonspecific LBP in older patients. A total of 32 patients, ages 60 and above, were randomly allocated to four groups: those treated with acupuncture, TENS, acupuncture and TENS and those in the control group. Each subject received a total of five treatments, provided once per week. Outcomes were measured by the use of a visual analog scale and the Roland – Morris Disability Questionnaire for ten weeks. The authors concluded that their study demonstrated the use of combined acupuncture and TENS to be effective in patients with CLBP as measured by the specified outcomes.

Jarzem P, Harvey E, Arcaro N, Kaczorowski J. Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain. *Journal of Musculoskeletal Pain*. 2005; 13(2): 3-9.

The goal of this research was to study the efficacy of TENS for the treatment of CLBP. Three hundred twenty four subjects with CLBP of at least 3 months duration and without leg symptoms were randomized into 4 treatment groups that included 3 different types of TENS and sham TENS. Follow up occurred after 2 and 4 weeks of treatment in the home. Outcome measures included those describing function, motion and depression. The authors concluded that TENS was no better than sham TENS for the treatment of CLBP without leg symptoms.

Kofotolis N, Vlachopoulos S, Kellis E. Sequentially allocated clinical trial of rhythmic stabilization exercises and TENS in women with chronic low back pain. *Clinical Rehabilitation*. 2008;22:99-111.

The purpose of this trial was to investigate the effectiveness of rhythmic stabilization exercises, transcutaneous nerve stimulation and the combination of these therapies upon females (aged 34-46) with chronic low back pain. Ninety-two participants were sequentially allocated into four groups: those receiving rhythmic stabilization exercises; those receiving a combination of rhythmic stabilization exercise and TENS; those receiving only TENS treatments; and those receiving placebo TENS. Treatments and/or training were administered five times per week for four weeks. Outcome measures included data pertaining to functional disability, intensity of pain, as well as trunk range of motion and endurance. Outcomes were recorded after completion of the treatment/training program, and at four and eight weeks after. The authors concluded that combining rhythmic stabilization and TENS was more effective than TENS alone, but not as effective as rhythmic stabilization alone in treating their study population.

Shimoji K, Takahashi N, Nishio Y, Koyanagi M, Aida S. Pain Relief by Transcutaneous Electrical Nerve Stimulation With Bidirectional Modulated Sine Waves in Patients With Chronic Back Pain: A Randomized, Double-Blind, Sham-Controlled Study. *Neuromodulation: Technology at the Neural Interface*. 2007;10(1):42-51.

The objective of this study was to compare the effectiveness of TENS using bidirectional modulated sine waves (BMW), to sham TENS in those with CLBP. Outcomes measured were relief of pain and increase in straight leg raising measurements. Twenty one subjects were randomly assigned to two groups: massage plus sham TENS or massage plus TENS using BMWs. Treatments were provided twice weekly for five weeks. The authors stated that their data suggested that there were neither long term effects of TENS by BMW nor interactive effects between massage and TENS.

Yokoyama M, Sun X, Oku S, Taga N, Sato K, Mizobuchi S, Takahashi T, Morita K. Comparison of Percutaneous Electrical Nerve Stimulation with Transcutaneous Electrical Nerve Stimulation for Long-Term Pain Relief in Patients with Chronic Low Back Pain. *Anesthesia & Analgesia*. 2004;98:1552-6.

The purpose of this study was to evaluate the effectiveness of percutaneous electrical nerve stimulation (PENS) treatment of chronic low back pain, using a TENS group as the control. Sixty subjects were randomly assigned to one of three groups: PENS treatment; PENS then TENS treatment; and TENS treatment. Each group was treated two times per week for eight weeks. Assessment of participants’ peak pain levels, physical impairment and analgesic consumption was performed during treatment and one and two months after. The authors concluded that repeated PENS therapy was more effective than repeated TENS therapy in relieving chronic LBP.

4. MEDCAC

A Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting was not convened on this issue.

5. Evidence Based Guidelines

At www.guidelines.gov, the National Guideline Clearinghouse, a search for `transcutaneous electrical nerve stimulation’ was performed.

Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.

Major Recommendations

Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (I-IV) are provided at the end of the "Major Recommendations" field.

Recommendations

1. Transcutaneous electric nerve stimulation (TENS) is not recommended for the treatment of chronic low back pain due to lack of proven efficacy (Level A, 2 Class I studies).
2. TENS should be considered for the treatment of painful diabetic neuropathy (Level B, 2 Class II studies).

Level A = Established as effective, ineffective, or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)

This guideline was also published as is further reviewed in this memorandum under the citation below:

Dubinsky RM, Miyasaki J. Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2010 Jan 12;74(2):173-6.

We also found one pertinent guideline: Managing musculoskeletal complaints with rehabilitation therapy: Summary of the Philadelphia Panel evidence-based clinical practice guidelines on musculoskeletal rehabilitation interventions. After a systematic review, the panel determined that “TENS ...showed no clinical benefit.”

In the initial public comments, CMS received references to two guidelines that made recommendations on the use of TENS in the treatment of CLBP. One of these guidelines was *The Practice Guidelines for Chronic Pain Management: An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine* published in April 2010. This guideline states that “TENS should be used as part of a multimodal approach to pain management for patients with chronic back pain and may be used for other pain conditions (e.g. neck and phantom limb pain).”

The other guideline was issued by *The National Institute for Health and Clinical Excellence (NICE)* in 2009 on *Low back pain: Early management of persistent non-specific low back pain*. The NICE low back pain guidelines recommendation was to “not offer transcutaneous electrical nerve stimulation (TENS).” However, the NICE guidelines went on to explain that “(t)hese guidelines have failed to recommend TENS as a treatment, not because of evidence that it does not work, but because there is no evidence that it is effective. The guideline development group did not find any large well-conducted large randomized controlled studies. TENS research should:

- Establish the most effective stimulation parameters for effective use.
- Assess pain relief when using TENS, overall daily pain, medication usage and healthcare consulting as outcomes in addition to disability.”

It should be noted that the duration of “chronic back pain” and “chronic low back pain” in the NICE management for low back pain guidelines and the chronic pain management guidelines developed by a collaboration of pain management and anesthesia specialty societies respectively, was not specifically defined as CLBP in a similar manner as done for the purposes of this NCD.

6. Professional Society Position Statements

National Institute of Neurological Disorders and Stroke: When LBP does not respond to more conventional approaches, TENS is identified as possible treatment option. [Retrieved January 3, 2011 from http://www.ninds.nih.gov/disorders/backpain/detail_backpain.htm]

National Institute of Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse: Although transcutaneous electrical nerve stimulation (TENS) is recognized as a complementary or alternative treatment modality for CLBP, “studies have shown that TENS treatments are not always effective for reducing pain.” [Retrieved January 3, 2011 from http://www.niams.nih.gov/Health_Info/Back_Pain/back_pain_ff.asp]

7. Expert Opinion

Following the submission of their public comments, members of the TENS academic and manufacturing community met with CMS to formally present the evidence referenced in their public comments. CMS met with Kathleen Sluka, PT PhD from the University of Iowa, a clinician and academician who has authored and co-authored clinical studies and textbooks on TENS, along with a few of her colleagues. CMS also met with TENS manufacturer RG Medical, representatives from the Neuroscience Device Alliance that represents the largest number of TENS manufacturers in the U.S., and with academician and TENS researcher Melissa Martinson MS PhD from the University of Minnesota. During these meetings CMS was provided an overview of the TENS technology and was presented with evidence from clinical studies referenced in their initial public comments on the use of TENS for the treatment of low back pain and posted on the CMS website.

8. Public Comments

As part of the NCD process, CMS uses initial public comments to obtain information regarding the topic under study. However, public comments that provide information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and have less evidentiary weight useful for making a coverage determination. Public comments that contain personally identifiable health information (PHI) are not published on our website. When possible, comments were posted on the CMS website with the PHI redacted. Comments primarily comprised of PHI were removed in their entirety. CMS takes into consideration all public comments and responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

A. Initial Comment Period 9/13/2011 - 10/13/11

Comments came from the following sources:

- 159 (44%) of the comments came from Medicare patients or on behalf of patients that use TENS for CLBP;
- 23 (6.5%) of the comments came from physical therapists and physical therapy assistants;
- 49 (14%) of the comments from physicians;
- 43 (12%) comments were submitted by other health care providers;
- 30 (8%) of the comments came from industry representatives;
- 5 (1%) of the comments came from researchers or persons at academic institutions;
- 13 (4%) of the comments came from medical centers and clinics;
- 2 (0.5%) of the comments came from hospitals;
- 6 (2%) of the comments came from specialty societies (which include the American Academy of Pain Medicine, the Puerto Rico Association of Physical Medicine and Rehabilitation, American Pain Foundation, the Florida Society of Interventional Pain Physicians, American Physical Therapy Association, and the American Society of Anesthesiologists; and
- 29 (8%) came from members the general public who did not identify a further affiliation.

Public comments may be viewed using the following link:
<http://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=256&ExpandComments=n&ver=5&NcaName=Transcutaneous+Electrical+Nerve+Stimulation+for+Chronic+Low+Back+Pain&bc=ACAAAAAAIAAA&>

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally by Medicare (§1862(l) of the Act).

In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, section 1862(a)(1) of the Act states in part that, with limited exceptions, no payment may be made under part A or part B for any expenses incurred for items or services:

- Which, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A)) or
- in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section. ((§1862(a)(1)(E)).

Section 1142 of the Social Security Act describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which diseases, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically.

Section 1862(a)(1)(E) allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate under section 1862(a)(1)(A), and where additional data gathered in the context of clinical setting would further clarify the impact of these items and services on the health of Medicare beneficiaries. CED, for example, allows CMS to determine that an item or service is only reasonable and necessary when it is provided within a research setting where there are added safety, patient protections, monitoring, and clinical expertise. For the readers’ convenience, the 2006 CED Guidance Document is available at <http://www.cms.gov/determinationprocess/downloads/CED.pdf>

As noted earlier, our review sought answers to the questions below. We have repeated them here for the convenience of the reader.

Analytic Questions:

In order to determine if TENS improves the clinically meaningful health outcomes of Medicare beneficiaries with CLBP (for purposes of this NCD, defined as LBP persisting for at least 3 months), we pose the following questions:

1. Does the use of TENS produce a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?

- 2. Does the use of TENS produce a clinically meaningful improvement in function in Medicare beneficiaries with CLBP?
- 3. Does the use of TENS produce a clinically meaningful improvement in any other health outcome in Medicare beneficiaries with CLBP?

If the answer to any of the questions above is affirmative, is the evidence sufficient to confidently identify the patient or device characteristics that predict improved health outcomes?

We evaluated the evidence related to these questions based on the results of the reviewed literature, the quality of the methodology used, and the overall generalizability of the studies to our beneficiary population.

§ 1862 (a)(1)(A) Analysis

Respectful of the historical Medicare coverage of the use of TENS for CLBP, we did not decide lightly to undertake this NCD reconsideration. The NCDs which pertain to the treatment of chronic pain were implemented in 1988 (see section 160.7.1 and 160.13 of the NCD Internet Only Manual (IOM)) and 1995 (see section 280.13 of the NCD IOM). These NCDs permitted Medicare coverage of the use of TENS for CLBP, but did not provide a national coverage analysis (NCA) that would describe the evidentiary basis of the decisions made. Nonetheless, it is both appropriate and responsible to periodically revisit old decisions and test their conclusions against the present day evidence base. Depending on the evolution of that evidence base over time, such testing could logically result in broader, narrower or unchanged coverage.

In 2010, the Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology [Dubinsky 2010] concluded that TENS was ineffective in the treatment of CLBP, based on its systematic review of the literature. Upon reading that analysis, CMS determined that it would be timely to reexamine the evidence surrounding the use of TENS to establish whether it is sufficient to warrant coverage of this modality for CLBP. The research articles considered for this NCA were published both prior to and after our previous NCD decisions were made, allowing us to review the evidence broadly to come to our proposed decision. The literature we apply to our questions on the use of TENS for CLBP is extensive in volume but has many limitations that prevent us from drawing confident and generalizable conclusions of benefit. Studies where authors claimed benefit were hampered by methodologic limitations. Other studies essentially reported no benefit, and the Kofotolis [2008] article concluded that TENS was less beneficial than rhythmic stabilization.

Because TENS for CLBP falls under the DME benefit and is ultimately purchased for chronic unsupervised use in the beneficiary’s home, the clinical significance of any therapeutic response is quite relevant to our review. When TENS is furnished as a professional service in a health care setting, the loss of response would be readily observable, and we would expect the practitioner to modify or stop TENS and seek other potentially more beneficial pain management strategies. The same cannot be said when a purchased TENS unit is self-applied in the home setting.

CLBP is defined for purposes of this NCD as persistent LBP for at least 3 months. Many studies were too brief in duration to speak to the clinically meaningful impact of TENS for CLBP, and were thus, not informative for the questions before us. The exclusion of studies where CLBP participants used TENS over a period of less than 4 weeks limited the amount of published literature on this topic. Few articles specific to the topic of TENS treatment of CLBP describe a protocol where the TENS unit was used and patient data was gathered for at least 4 weeks. The six RCTs summarized in Table 1 met these criteria.

The five systematic reviews and single meta-analysis we summarized above are more problematic. Because these articles reviewed literature that did not fit our inclusion criteria as stated, their conclusions are based on evidence that we do not consider relevant to the questions posed in this analysis. Therefore, we believe it inappropriate to include the results of this literature in our review and we remove them from consideration in our analysis.

Study Results

1. Does the use of TENS produce a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?

As noted in Table 2, the lengths of treatment in the reviewed investigations ranged from 4 to 8 weeks. During that time, only in Yokoyama [2004], did the VAS score between pretreatment and the end of treatment decrease significantly with the use of TENS. Notable is the fact that there was no sham TENS in this clinical trial. This result is contrasted with results from the following studies:

- In Deyo [1990], there was no difference in outcomes noted between those receiving active TENS treatment and sham TENS.
- In Itoh [2009], after 5 weeks of treatment, there were no significant changes in VAS scores as compared to pre- treatment in the TENS group.
- In Kofotolis [2008], after 4 weeks of treatment, discomfort as measured by the Borg verbal pain rating did not demonstrate a significant difference between those who received TENS and sham TENS. Also, there was no difference between pre- and post-treatment measurements of back pain severity in those who received TENS and sham TENS.
- In Shimoji [2007], one week after 5 weeks of treatment with massage plus TENS, or massage plus sham TENS, there was no significant difference in pain ratings between those individuals who received the active versus the sham TENS.

Therefore we conclude that, based on the available evidence, TENS does not produce a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP, since a sham unit appears to provide equivalent analgesia.

2. Does the use of TENS produce a clinically meaningful, improvement in function in Medicare beneficiaries with CLBP?

In the presence of chronic pain, rarely is the complete eradication of discomfort a realistically achievable goal of treatment. Instead the aim of treatment is to make the pain more tolerable and, potentially, to increase function [Bloodworth 2000; Stanos 2007].

Because individuals differ in their perception and tolerance of pain, and other factors may contribute to a more global sense of suffering, the study of pain relief can be challenging. A patient may, for example, perceive and self-report improvement after placebo or sham treatment. The intensity or tolerability of pain may vary temporally, even over the course of a single day due to factors unrelated to the pain-inciting physical condition itself. To reduce biases that may lead to erroneous conclusions about cause and effect, CMS believes that in combination with pain reduction, more persuasive studies in this field should include measures that track objective measurable improvement from the use of TENS; improvements, for example, that reflect the enhancement of the performance of activities of daily living (ADLs) and instrumental activities of daily living (IADLs).

Some of the authors in our reviewed studies did attempt to correlate TENS usage with outcome measures that reflect such a positive improvement in the lives of their patients. The pertinent results are as follows:

- In Deyo [1990], at the end of 4 weeks of treatment, there were no clinically important or statistically significant differences in the functional outcomes of those who received TENS versus sham TENS. Functional measures included the overall modified Sickness Impact Profile score (physical dimension and psychosocial dimension scores) and a self-assessed level of activity.
- In Itoh [2009], by the end of treatment, the TENS group reported lower Roland Morris Questionnaire (RMQ) scores than the control group, but these differences were not statistically different.
- In Jarzem [2005], functional measure scores (McGill activity scale, McGill work scale and the RMQ) were no different between those who received TENS and sham TENS at the end of treatment.
- In Kofotolis [2008], the change in Oswestry Index scores between pre-treatment and the completion of treatment with TENS were not statistically significant. The scores were also no different from those gathered after treatment with sham TENS.
- In Yokoyama [2004], a physician assessed the patient’s degree of impairment on a multiple choice form. There were no statistically significant differences in these scores as compared to baseline throughout the entire study for those treated with TENS.

Therefore we conclude that, based on the available evidence, TENS does not produce a clinically meaningful increase in function in Medicare beneficiaries with CLBP.

3. Does the use of TENS produce a clinically meaningful, improvement in any other health outcome in Medicare beneficiaries with CLBP?

Authors have attempted to expand the breadth of outcome measures beyond that of pain ratings and functional scales in order to capture other relevant aspects of chronic disease that may be improved by the use of TENS. These outcome measures include:

- Physiologic parameters such as strength, range of motion (ROM), endurance
- Decrease in medication usage
- Changes of mood or emotion
- Usage of medical services

CMS believes that, while interesting, outcome measures that document changes in isolated physiologic parameters alone, such as strength, ROM and endurance are not sufficient to determine if TENS has a clinically meaningful benefit. Though improvements in these parameters may coincide with benefit, they do not necessarily assess the patient’s capacity to perform on a day-to-day basis within their chosen environments. Instead, we believe that functional outcomes provide a more accurate indication of the clinical significance of a TENS treatment.

We recognize that the achievement of comparable pain relief with reduced need for medication is also an important potential outcome. However, CMS believes that assessment of reduced medication usage would require rigorous methodology in order to determine if this is indeed a predictable and generalizable benefit of TENS for CLBP. All medications have the potential to produce adverse side effects. For those taking medications to reduce the discomfort of CLBP, these side effects can range from constipation to gastrointestinal bleeding to the cerebral changes that affect judgment, affect, mood, cognition and orientation. Minimizing the potential for such adverse events may be a major goal of improved health care.

Similarly our commenters believe that decreased dependence on the health care system, and specifically the reduction in consumption of medical resources, may also be an indication of improved health outcomes in patients with chronic pain. CMS believes that when a patient’s dependence on the medical system is reduced, it may provide more opportunities for the patient to pursue his or her chosen activities, and thereby increase the individual’s overall independence and quality of life.

Three articles met our inclusion criteria and reported outcome measures that we believed to be meaningful in this context. They provided the following results:

- In Deyo [1990], the use of medical services in all treatment groups was tracked. There were no reported statistically significant differences in this measure between the TENS versus the sham TENS groups at the end of treatment.
- In Jarzem [2005], the authors used the Zung Depression Scale to measure depression in patient groups during the treatment period. Patients also kept diaries to determine frequency of medication usage and to track the use of ancillary care. The authors reported no difference in these measures between those subjects receiving any type of TENS and those receiving sham TENS.
- In Yokoyama [2004], patients receiving TENS demonstrated no statistically significant differences in dosages of non steroidal anti-inflammatory drugs (as measured by numbers of pills consumed) throughout treatment with TENS. (There was no mention of narcotic use in these patients).

Therefore we are unable to conclude, based on the available evidence, that the use of TENS produces a clinically meaningful, improvement in any of these health outcomes in Medicare beneficiaries with CLBP within the scope of this decision.

Methodologic Limitation of the Evidence

Study Duration

The research designs in the reviewed literature limit our ability to evaluate the impact of continuous use of TENS on health outcomes in the Medicare beneficiary population. Moreover the study designs did not allow us to evaluate possible dampening of patient response to TENS over time.

We believe that in order to demonstrate a clinically meaningful impact of TENS on CLBP, it is important to understand the temporal relationship of TENS use to its putative benefits. For example, does TENS application at a point in time produce a benefit compared to a pre-treatment baseline and does any benefit extend for some significant period of time after removal? Or, does TENS produce a benefit only during the period when it is applied and active? To use a drug analogy, does TENS display a therapeutic profile like an antibiotic course where sustained relief of the infection follows a defined period of treatment or is it more akin to an antihypertensive medication where ongoing use is required to maintain a benefit?

It is also important to understand whether the putative benefits of TENS are affected by the treatment setting. Specifically, are claimed improvements in health outcomes of TENS dependent on the physical therapy services that are furnished concomitantly? Or does the available evidence give us confidence that these claims are generalizable to unsupervised use in the home setting?

To the best of our knowledge, there is one study [Marchand 1993], (Table 2) that begins to address this issue. However, we find this study less persuasive in the context of our review for several reasons.

1. The study enrolled subjects who fall outside of the scope of this reconsideration; specifically it included subjects with specific rheumatologic diagnoses.
2. The study size was modest overall and the active treatment arm itself was small. Of the total 42 subjects, 16 were controls and received neither other active treatment nor TENS device treatment.
3. During the period of active treatment, TENS, but not placebo TENS was reported to decrease pain intensity in a sustained manner. However, while the study was planned for two treatments per week for 10 weeks (20 treatments) data were only reported for the first 16 treatments. It is thus not clear whether the reported impact of TENS during the active treatment period itself was maintained for the last 2 weeks.
4. The study setting for the active treatment was a laboratory rather than the subjects’ homes.
5. Ultimately the same long term effect, months after the treatments ended, was reported in patients treated with active TENS and placebo TENS. The authors speculated that an increase in physical activity as a result of a decrease in pain may have produced this outcome, but physical activity was not systematically addressed in the report.

Other authors have tried to address the temporal relationship of TENS to its purported outcomes. Bjordal [2011] notes that there is a general consensus that the optimal benefit of TENS is achieved during stimulation. This author also states that the value of the results of TENS trials where treatment effects have been measured beyond the period of stimulation is questionable.

This is particularly pertinent in light of the expanding literature that suggests the effects of TENS may in some part, be mediated by endogenous opioids and other pain modulating substances in the body [Kalra 2001; Liebano 2011; Leonard 2011]. It is postulated by some [Leonard 2011; Liebano 2011; Sluka 2009; DeSantana 2008] that repeated application of TENS may produce tolerance to its analgesic effects because of the development of tolerance to the opioid effects of TENS. While to the best of our knowledge the phenomenon of TENS tolerance has not been studied specifically in individuals with CLBP, the potential lessening of efficacy of TENS when applied in repeated long term dosages is pertinent to this NCA. These observations may explain why in some clinical studies it has been noted that though patients may initially respond well to TENS in terms of pain relief, there can be a significant drop in efficacy over time [Tulgar 1991(b); Fishbain1996; Johnson 1991; Johnson 1992]. For example, in one study of individuals with a variety of chronic pain conditions [Johnson 1991], 32% of the patients reported a decline in TENS efficacy from the time the unit was issued (at least a 3 month duration). These statistics included 13.7% of the patients who reported no relief at all from these units by the end of the study, even though they had experienced a “successful” trial session.

CMS notes potential for significant bias that limits our confidence in the reported results of this body of literature.

Important methodologic limitations were present in the reviewed literature that could have affected reported outcomes (Table 3). For example, several of the studies did not provide a sham TENS device. These studies compared TENS devices to other exercise treatments and modalities as noted in Table 1. We believe that a sham TENS control is important to minimize the bias of a placebo effect.

Sham devices do not completely guarantee appropriate blinding of the patient or assessor. Patients in a clinic may talk among themselves and determine who has a working device. Furthermore, in the particular case of TENS, subjects with sham TENS must be educated so that those who do not feel the sensation of the working device are just as likely to have a positive response to the therapy as those who do perceive the TENS sensation. However, those previously familiar with a TENS or other devices providing electrical stimulation may be harder to persuade, and their pain/functional status may be influenced by their recognition of the true or sham device. Therefore, in order to attempt to determine whether patient blinding in a device study was actually successful, CMS believes an evaluation should be made at the end of treatment to determine subject thoughts as to that treatment they received (active versus sham TENS) and compare their response to the real treatment. Only Deyo [1990] fulfilled this research step (Table 3).

Furthermore, randomization does not entirely eliminate the possibility that the various arms of the study will differ by factors that potentially affect the outcome of the study. Known prognostic factors should be identified and analyzed to determine if by chance or by design flaw, differences are found between the baseline characteristics of the study and control populations. Though the authors of the above trials compared the characteristics of the study and control groups to determine similarity between the two, the comparisons varied widely. For example, in Itoh [2009], it was stated that, “No significant difference was found in baseline variables including age, disease, pain duration and VAS among the four groups.” No table of baseline characteristics nor levels of statistical significance were supplied to support that statement. In Jarzem [2005], it was stated that the four treatment groups were not significantly different in the categories of ... “job enjoyment, stress level, heavy laborers, use of vibrating equipment, smoking history, weight loss, back surgery, medication needs or compensation claims in the past.” Again, no table of baseline characteristics nor levels of statistical significance were provided to support the statement, but the demographic comparison was more detailed than that of the former study and more likely in our opinion to control for potential confounders that would affect the prognosis of the study subjects and thus the outcome of the study.

Additionally, in a device study it is important to document the case volume, expertise and other pertinent qualifications of the treating clinicians. Both treatment and evaluation can be affected by differing levels of clinician qualifications and experience. Such differences may present a significant threat to the validity of the trial. There should also be a clear description of blinding of those who administer the interventions and/or record/conduct evaluations in a well performed study [Boutron 2008]. For the most part, the reviewed studies did not provide this information (Table 3).

From our evaluation of the above criteria, we conclude that the risk of bias is high in many of the trials we examined and therefore the overall strength of the reviewed evidence is low.

Intent to treat (ITT) analyses

Patients may drop out of a trial for a number of reasons, including untoward effects of the intervention (e.g., symptomatology of CLBP and/or response to treatment) [Akl 2009]. In TENS studies this could have lead to an over or underestimate of the intervention’s impact. Most of the studies described the reasons for patient loss to follow up (LFU). However, none of the papers provided descriptions of the last known outcomes of the LFU patients and only one study included an analysis that took into account possible outcomes of LFU patients. CMS believes that all patients enrolled in a study should be accounted for, and using an intent to treat analysis helps to more accurately gauge the impact of an intervention. There are several methods by which to impute outcomes in those participants who have dropped out of a study. If, however, the outcomes measures for LFU patients cannot be included in the final analysis, then at least a detailed discussion of the implications of the missing data is necessary [Cochrane 2012].

Generalizability/applicability to use in the Medicare population

As we reviewed the literature we were struck by the heterogeneous mix of patient populations, electrical characteristics of the devices studied, comparators used and outcomes measured (Table 1). These variable characteristics posed additional obstacles to assessing whether or not TENS therapy improves health outcomes in individuals with CLBP. It also hampers our ability to predict those factors that might determine the characteristics of patients who would have the most favorable outcomes with the usage of TENS.

Furthermore, when extrapolating evidence from a clinical trial to a clinical setting, CMS believes it is important to establish that the evidence gathered is relevant to our beneficiary population and the setting in which those individuals are treated. We note that Medicare claims data as illustrated below, demonstrate that of all the individuals who purchased new TENS units, approximately one-third are obtained by individuals below the age of 65, and two-thirds are obtained by individuals above the age of 65. We believe that the studies included in our evidence base reasonably attempted to represent these population groups.

However, as noted above, TENS use is directed towards the home setting once the patient has been educated in the workings of the device. But we note that the home was the main setting of TENS application in only two studies (Table 1). We do not believe that the results of treatment that occurs in a clinical setting under the hands-on care of a qualified therapist would necessarily be representative of the treatment result when TENS is self administered in a home setting.

We also note that three of the studies included in this review originated from Japan [Itoh 2009; Shimoji 2007; Yokoyama 2004] and one was from Greece [Kofotolis 2008]. Differences in the cultural attitudes and experiences towards pain in individuals from other countries compared to individuals from the United States may influence the outcomes of the research [Davidhizar 2004; Johnson 1997]. Though this is not necessarily a fatal flaw of these studies, these differences may limit the generalizability of the conclusions from these trials to the Medicare population.

In summary, based on the additional evidence that has been published (see section VII) since the original decision, we do not believe that the updated evidence base supports the coverage of TENS in CLBP. We, therefore, propose noncoverage under section 1862(a)(1)(A) of the Act.

§1862(a)(1)(E) Analysis

We recognize that the absence of conclusive evidence of benefit does not equate to conclusive evidence of no benefit. We also appreciate the significant burden of CLBP on the beneficiary population, which may lead to frustration on the part of patients, their treating practitioners and their caregivers. However, this frustration should not be the underlying reason for coverage of an item or service in circumstances where treatments are not known to be beneficial.

Therefore, we believe that it is appropriate to use coverage with evidence development (CED) to support the generation of more informative evidence. As explained in the 2006 CED guidance document, cited above, CED facilitates development of additional evidence from approved clinical studies in order to clarify the impact of an item or service on the health outcomes of Medicare beneficiaries. CED enables this additional development of evidence within a research setting where there are added safety precautions, patient protections, monitoring and clinical expertise.

As a foundation for CED, CMS has emphasized three factors relevant to the appropriateness of a CED coverage determination. The first is that the basic safety of the proposed item or service must be assured. In the case of TENS for the treatment of CLBP, adverse events are rare (see Table 1) and usually mild. The basic safety of the patient when using TENS is not in question here.

A second is the potential benefit of the proposed item or service for Medicare beneficiaries. As noted above, TENS has been historically, thought to relieve chronic pain. If TENS can in fact have this impact, it could potentially also lead to improved patient function, decreased medication usage and decreased patient dependence on other aspects of the health care system. While we have stated that the evidence as yet is insufficient to support these outcomes, we agree with the importance of investigating these goals and want to encourage future research on these topics through the use of CED.

The third is the difficulty of conducting adequate trials. Bennett [2011] and Bjordal [2011] note that while conventional sources of bias do confound the TENS literature (e.g. lack of blinding; incomplete accounting for study drop outs/withdrawals, etc.), the characteristic of 'low implementation fidelity' may also account for the inconclusive findings in this body of literature.

As various authors explain, low implementation fidelity of a study suggests that it contains sources of bias that may lead to an underestimation of treatment effect. Bennett [2011] details various examples of low fidelity in previously conducted TENS trials such as:

- the lack of information provided to patients concerning the sensations they may experience with the TENS device
- the lack of instruction received by patients concerning how to adequately self-administer TENS
- the lack of assessment of compliance in TENS trials
- the lack of reporting of concurrent use of pain medications and comparable assessment of analgesia between study groups
- the inadequacy of reporting of the pattern and duration of TENS use
- the adequacy of the TENS intervention itself (including electrical parameters, treatment duration/frequency, electrode placement, etc).

CMS acknowledges the difficulties that have plagued the development of an informative TENS evidence base and believes that an opportunity should be afforded to address the limitations of previous studies.

In summary, we believe the study of the use of TENS in the treatment of CLBP is an appropriate topic for CED. Specifically, we propose CED to answer the following questions:

1. Does use of TENS provide a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
2. Does use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?
3. Does use of TENS provide a clinically meaningful reduction in other medical treatments or services used in the medical management of CLBP?

CMS believes that systematic, protocol-driven data are important to increase the likelihood that beneficiaries achieve improved health outcomes. Care provided under these protocols generally involves greater attention to appropriate patient evaluation and selection, as well as the appropriate application of the technology. These additional protocol-driven data may alter the course of patient treatment based on the best available evidence, and may lead a physician to reconsider the use of the item or service or otherwise alter a patient’s management plan, potentially improving health outcomes.

Duration of CED coverage for TENS

CMS considers the results of all CED clinical studies critical in the evolution of medical technology and in the timely evaluation of the benefit of items and services covered under CED. CMS proposes to cover under CED the use of TENS for CLBP when furnished within the clinical study protocols.

Preferably, a clinical study that evaluates the health outcomes of the use of TENS under CED would have the following characteristics:

- The trial exhibits a randomized control design.
- The endpoints are pre-specified in the protocol.
- The method of the TENS application is designed to achieve a maximum durable benefit.
- There is a detailed description of the TENS application, including type of TENS, electrical parameters being used, frequency and duration of device usage and account of electrode placement.
- The control group is randomized to receive a sham unit.
- The analysis follows an intent-to-treat principle.
- Missing data should be accounted for.
- The study participants use the TENS units to achieve outcomes specific and appropriate to the individual setting (e.g. home, therapy clinic, etc).
- The study is adequately blinded – the study subjects, health care providers and evaluators are blinded.
- The TENS settings are monitored.
- Other therapies (including medications, physical therapy, etc.) for CLBP are controlled for and associated medical services are tracked.
- The exclusion criteria are appropriate.
- The sample size is adequate to detect an appropriate effect size based on pre-specified meaningful outcomes.
- The study results may be generalized to the Medicare population. This means that the sample would, at minimum, contain Medicare-relevant age and gender distributions, that are shown in the tables below:

Age distribution of Medicare beneficiaries purchasing a new TENS unit, 2006-2010

	Year			
	2006	2007	2008	2009
	2010			

	2006	Year 2007	2008	2009	2010
Under 25	59	86	69	121	112
25 - 34	721	1,158	1,246	1,418	1,676
35 - 44	2,659	4,410	4,628	4,712	5,383
45 - 54	5,060	8,394	9,103	9,715	11,354
55 - 64	5,275	8,793	9,491	9,981	11,977
65 - 74	15,327	23,578	25,082	27,824	31,394
75 - 84	9,328	14,569	14,695	15,793	17,922
85 - 94	2,084	3,402	3,641	4,073	4,710
95 and older	66	108	124	168	177
Total	40,579	64,498	68,079	73,805	84,705

Reason for eligibility of Medicare beneficiaries purchasing a new TENS, 2006-2010

	2006	Year 2007	2008	2009	2010
Aged without ESRD	26,714	41,564	43,435	47,683	54,026
Aged with ESRD	136	181	227	280	298
Disabled no ESRD	13,581	22,471	24,112	25,453	29,880
Disabled with ESRD	98	205	211	247	329
ESRD only	50	77	94	142	172
Total	40,579	64,498	68,079	73,805	84,705

Gender of Medicare beneficiaries purchasing a new TENS, 2006-2010

	Year				
	2006	2007	2008	2009	2010
Male	12,154	19,415	20,639	23,000	26,684
Female	28,425	45,083	47,440	50,804	58,020
Total	40,579	64,498	68,079	73,804	84,704

Source: Part B Medicare claims files

Disparities
Studies performed in the United States should also provide evidence about benefits or harms related to other population classifiers that have been associated historically with healthcare access or outcome disparities, such as gender, age, sexual orientation and religion, and encourages additional studies in which such associations might be studied. We find it helpful when clinical studies include data on racial and ethnic factors where they are relevant to the conclusions that may be drawn about the impact of the investigational item or service.

IX. Conclusion

CMS proposes coverage for Transcutaneous Electrical Nerve Stimulation (TENS) for chronic low back pain (CLBP) only when all of the following conditions are met.

A. For the purposes of this decision CLBP is defined as:

- a. an episode of low back pain that has persisted for three months or longer; and

- b. is not the result of certain well-defined diseases that may contribute to low back pain but which are not primarily low back syndromes.

For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom. Certain systemic diseases, e.g. rheumatoid arthritis, multiple sclerosis etc, manifest many debilitating symptoms of which low back pain is not the primary focus. We believe that the appropriate management of these types of diseases is guided by a systematic strategy aimed at the underlying causes. While TENS may infrequently be used adjunctively in managing the symptoms of these diseases, it is clearly not the primary therapeutic approach.

B. The patient is enrolled in a prospective clinical study that addresses one or more aspects of the following questions in a randomized, controlled design using validated and reliable instruments. This can include randomized crossover designs.

- 1. Does the use of TENS provide a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
- 2. Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?
- 3. Does the use of TENS provide a clinically meaningful reduction in other medical treatments or services used in the medical management of CLBP?

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- a. The principal purpose of the clinical study is to test whether TENS potentially improves the participants’ health outcomes.
- b. The clinical study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- c. The clinical study does not unjustifiably duplicate existing studies.
- d. The study design is appropriate to answer the research question being asked in the study.
- e. The clinical study is sponsored by an organization or individual capable of successfully executing the proposed study.
- f. The clinical study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46.
- g. All aspects of the clinical study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- h. The clinical study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
- i. The clinical study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals.
- j. The clinical study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- k. The clinical study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors

(<http://www.icmje.org>). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

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The clinical study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

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The clinical study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

We are requesting public comments to this proposed decision pursuant to section 1862(l) of the Social Security Act (the Act). After consideration of the public comments and any additional evidence, we will issue a final determination responding to the public comments consistent with §1862(l)(3) of the Act.

APPENDIX A

TABLE 1: TENS Evidence Tables

Study: Deyo 1990	
Study Design	<div><div>•Random block assignment to one of 4 groups</div><div>•Assignments drawn from sealed envelopes and determined by a table of random numbers</div><div>•Subject and evaluator blinded to TENS/sham TENS</div><div>•Setting for interventions was predominantly the home</div><div>•Compliance checked for at home regimens</div><div>•At completion of 4 weeks treatment, data analyzed for 125/145 subjects (14% drop out rate)</div></div>
Characteristics of Participants	<div><div>•Ages 18-70 years</div><div>•Inclusion criteria: LBP of at least 3 months duration</div><div>•Exclusion criteria: history of cancer; requiring corticosteroids or anticoagulants; maximal pain above T-12; use of a cardiac pacemaker; known heart disease; severe co-existing condition; previously unevaluated neurological deficit; inability to return for appointments; inaccessible by telephone; inability to speak English; individuals seeking/receiving disability compensation; previous use of TENS</div></div>
Intervention	<div><div><div><i>Treatment groups:</i></div><div>•TENS alone, TENS + exercise, exercise with sham TENS , sham TENS alone (TENS/sham TENS units were identical)</div></div><div><div><i>Concurrent therapy</i></div><div>•Twice per week, all subjects received moist heat therapies, adjustments in electrode placement, and written/oral advice in body mechanics in a clinic environment</div><div>•Recommended that electric heating pads (loaned to all participants) be used twice daily at home</div><div>•Other treatments (medications, physical therapy, other health care providers) were not proscribed</div></div><div><div><i>Electrical parameters of treatment:</i></div><div>•Patients in the TENS group received conventional high frequency TENS for 2 weeks (80 – 100 pulses per second, amplitude = 30), then experienced acupuncture –like TENS (2-4 pulses per second, amplitude = 100). Patients self selected preferred mode of TENS for 2nd two weeks of study.</div><div>•Modulated pulse rate mode used for all TENS</div></div><div><div><i>Electrode placement:</i></div><div>•Four carbon impregnated electrodes (5.5 cm diameter) initially placed over area of most severe pain; moved as necessary to optimize pain relief</div><div>•For participants with radiating pain, electrodes placed on leg and back</div></div><div><div><i>Frequency/duration of treatment sessions:</i></div><div>•All subjects receiving TENS/sham TENS received instructions for home use, at least 45 minutes, 3 times per day</div><div>•Exercise participants received a uniform set of 12 exercises to be performed daily</div><div>•In addition to daily home treatment assignments, patients were seen at medical facility 2 times per week for hot packs, adjustment of electrode placement, body mechanics advice.</div></div></div>
Outcome Measures	<div><div>•Modified Sickness Impact Profile</div><div>•Self assessment of change of activity level (increased; decreased; unchanged)</div><div>•Pain overall improvement rating (6 point ordinal pain scale;1= entirely gone; 6 = much worse)</div></div>

	<ul style="list-style-type: none">•10 cm visual analogue pain scale•10 cm visual analogue scale of improvement (0-100%)•Ordinal scaleof pain frequency (1 = never; 5 = all the time)•Straight leg raising ability•Spinal and hip flexion as measured by distance of fingertips to floor on maximal forward flexion•Schober’s test•Use of medical services•Success of blinding
Timeline of Treatment and Follow up	<ul style="list-style-type: none">•Treatments administered for 4 weeks•Outcomes gathered at 2 and 4 weeks of treatment and 2 months after completion of intervention
Adverse events	<ul style="list-style-type: none">•Approximately one third of participants reported minor skin breakdown at the TENS electrode sites.•One subject required the discontinuation of sham TENS due to severe dermatitis.
Results	<ul style="list-style-type: none">•The authors concluded that there were no clinically important or statistically significant differences in any outcome measuring pain, functional status, physical parameters or the use of medical services, at the end of 4 weeks of treatment between the participants using true versus sham TENS. Among the subjects receiving true TENS, 100% guessed that they received the functioning units. Of those receiving sham TENS 84% guessed that they received a functioning unit (but with a lesser degree of certainty).

Study: Itoh 2009

Study Design	<ul style="list-style-type: none">•Random block assignment to one of 4 groups•Allocation table generated by Sample Size, version 2•Not a blinded study•Setting for intervention was a medical institution•Final data analyzed on 26/32 subjects (19% drop out rate)
Characteristics of Participants	<ul style="list-style-type: none">•Ages 61-81 years•Lumbar or lumbosacral pain for six months or longer•Inclusion criteria: no radiation of LBP, normal neurologic findings of lumbosacral nerves; not receiving acupuncture treatment for more than 6 months,•Exclusion criteria: Major trauma or disease; receiving conflicting or on-going co-interventions•Participants under drug regimens were included if there were no changes in medications or dosages for one month or longer
Intervention	<p><u>Treatment groups:</u></p> <ul style="list-style-type: none">•Acupuncture (ACP), TENS, acupuncture and TENS (A&T), control (CT) <p><u>Concurrent therapy:</u></p> <ul style="list-style-type: none">•No other co-interventions were being taken by participants during the study period(including analgesics, anti-inflammatory medications, or poultices containing methylsalicylic acid <p><u>Electrical and other parameters of treatment:</u></p> <ul style="list-style-type: none">•ACP: received treatment at selected acupoints; needles were inserted into the muscle for a depth of 10 mm using a ‘sparrow specking technique’ by trained and experienced acupuncturists; when the patient felt dull pain or obtained de qi, the needle manipulation was stopped and the needle was left in place for 10 minutes more•TENS: single channel TENS unit producing a premixed amplitude modulated frequency (122 Hz) generated by 2 medium frequency sinusoidal waves of 4.0 and 4.122 kHz; TENS intensity adjusted to produce a tingling sensation 2-3 times the participant’s sensory threshold•ACP&T: treatments of ACP and TENS above were combined•CT: use of topical poultice containing methylsalicylic acid as necessary <p><u>Electrode placement (TENS):</u> Two surface electrodes of differing sizes (ratio 1:7) used; smaller electrode placed at point of most tenderness and larger electrode placed the near side of the point</p> <p><u>Frequency/duration of treatment sessions:</u></p> <ul style="list-style-type: none">•Once per week•Each individual treatment of ACP or TENS was administered over a 15 minute session•ACP + TENS was administered as 15 minutes of TENS, then 15 minutes of ACP
Outcome Measures	<ul style="list-style-type: none">•Pain intensity VAS (0-100 mm)•Roland Morris Questionnaire (RDQ)
Timeline of Treatment and Follow up	<ul style="list-style-type: none">•All patients received specified treatment for 5 weeks•Follow up was for 10 weeks after first treatment•VAS measured immediately before 1st treatment and then again at 1,2,3,4,5, and 10 weeks later (before receiving treatment if indicated)•RDQ measured immediately before 1st treatment and then again 5 and 10 weeks later (before receiving treatment if indicated)
Adverse events	<ul style="list-style-type: none">•One subject in A&T group dropped out secondary to deterioration of symptoms
Results	<ul style="list-style-type: none">•The authors reported that mean VAS and RDQ scores decreased in all groups during treatment. However during the 5 weeks of treatment the only statistically significant reduction in mean VAS between pre-treatment and week 5, was in the A&T group. At the same time point, the RDQ scores were lower in the ACP. TENS, and A&T groups as compared to the CT group. However, there was no significant difference in RDQ scores between the treatment groups.

Study: Jarzem 2005

Study Design	<ul style="list-style-type: none">•Randomized into 4 groups by random number tables•Patients were assigned to the group in consecutive fashion depending on the order of enrollment•Physiologic data gathered by blinded observer; exercise program provided by blinded physiotherapist•Setting for intervention was predominantly the home•Compliance checked for at home regimens•Final data analyzed for 324/350 subjects (7% dropout rate)
Characteristics of Participants	<ul style="list-style-type: none">•Ages between 18 – 70•Continuous LBP (without leg symptoms)for at least 3 months•Inclusion criteria: Ability to come to required visits over the treatment period•Exclusion criteria: Maximal pain above T12; previous use of TENS; seeking disability compensation; history of cancer, corticosteroid or anticoagulation use; sciatica; implanted pacemaker; concomitant physiotherapy or chiropractic therapy; surgery within past 3 months; major illness, pregnancy
Intervention	<p><u>Treatment groups:</u></p> <ul style="list-style-type: none">•Conventional TENS, acupuncture TENS, biphasic (nu-wave) TENS and sham TENS•All groups provided with identical units. <p><u>Concurrent therapy:</u></p> <ul style="list-style-type: none">•All patients received an identical exercise program•Reported that no patient had been chronically dependent on narcotics <p><u>Electrical and other parameters of treatment:</u></p> <ul style="list-style-type: none">•Unspecified except that original intensity was adjusted to the threshold point below noxious stimulation as per manufacturer recommendations (just below an intensity that resulted in muscle twitching)•Patient could adjust intensity over course of study <p><u>Electrode placement (TENS):</u></p> <ul style="list-style-type: none">•Electrode placement optimized per manufacturer instructions and patient needs, then adjusted during study per patient preference <p><u>Frequency/duration of treatment sessions:</u></p> <ul style="list-style-type: none">•Daily/weekly treatment recommendation was unspecified•Subjects used, on average, TENS units for “close to” 88 hours during the study; an average daily use of approximately 188 minutes
Outcome Measures	<ul style="list-style-type: none">•Roland disability scale•McGill Functional Questionnaire (work and activity scales)•Pain questionnaire used to gauge changes in pain patterns•Zung depression scale•Diary to record ancillary care, pain intensity as measured by a visual analogue score, medication usage, TENS usage, etc•Hip and lumbar flexion•Straight leg raising•Isolift scoring
Timeline of Treatment and Follow up	<ul style="list-style-type: none">•Patients were taught to use TENS at home and then seen at 2 and 4 weeks for follow up.
Adverse Events	<ul style="list-style-type: none">•None reported
Results	<ul style="list-style-type: none">•The authors concluded that after one month, TENS was no better for the treatment of CLBP without sciatica than was placebo. It is noted that VAS were not analyzed secondary to incomplete data.

Study: Kofotolis, 2008

Study Design	<ul style="list-style-type: none">•Sequential allocation into one of 4 groups•Single blinded•Setting for interventions was a medical institution•Final data analyzed for 88/92 subjects
Characteristics of Participants	<ul style="list-style-type: none">•Females, ages 34 – 46 years•Failed a period of “rest” for 6 months and had received other forms of therapeutic treatment•Inclusion criteria: complaint of low back pain (a) during and/or after activity and/or (b) during and/or after sitting and/or (c) during stair climbing•Exclusion criteria: surgery, sciatica, radiographic abnormalities (i.e. spondylolysis, spondylolisthesis, lumbar scoliosis greater than 10 degrees), injuries of the trunk, muscle and tendon ruptures, previously exposed to rhythmic stabilization or TENS
Intervention	<p><u>Treatment groups:</u></p> <ul style="list-style-type: none">•Rhythmic stabilization; rhythmic stabilization and TENS; TENS alone; placebo stimulation <p><u>Concurrent Therapy:</u></p> <ul style="list-style-type: none">•No additional physiotherapy provided during treatment period <p><u>Electrical and other parameters of treatment:</u></p>

	<ul style="list-style-type: none"> •Rhythmic stabilization exercises: 3 sets of 15 repetitions of alternating trunk flexion/extension isometric contractions at maximal resistance against resistance held for 10 sec provided by the same therapist (with prescribed rest sessions between each pattern and set) •TENS: 40 – 45 minutes of TENS delivered in the prone position with a unit providing pulse duration of 200 µsec and frequency of 4Hz at a ‘strong but comfortable’ level of stimulation •Rhythmic stabilization and TENS: subjects received 20 minutes of TENS , rest, then 20 minutes of rhythmic stabilization •Placebo TENS – received at same site and for same duration as TENS group using identical units <p><u>Electrode Placement (TENS):</u></p> <ul style="list-style-type: none"> •Four rubber electrodes (2 cm x 3 cm) placed on fascia thorocolumbalis and approximately 10 cm proximal, along midline of muscle (directly over site of pain) <p><u>Frequency/Duration of treatment sessions:</u></p> <ul style="list-style-type: none"> •Participants were trained 5 times per week •See above for specifics of each treatment program
Outcome Measures	<ul style="list-style-type: none"> •Oswestry Low Back Pain Disability Questionnaire •Borg verbal rating pain scale (0 = normal, 10 = emergency) •Range of motion and endurance of trunk extension and flexion
Timeline of Treatment and Follow up	<ul style="list-style-type: none"> •Baseline measures were obtained one week prior to training •Follow up measures gathered at end of treatment program (4 weeks), then 4 and 8 weeks after
Adverse effects	<ul style="list-style-type: none"> •None reported
Results	<ul style="list-style-type: none"> •The authors concluded that short term rhythmic stabilization exercise is effective in the treatment of women with CLBP. Furthermore they stated that treatment with TENS appears to be more effective than treatment with placebo TENS, but less effective than a combination treatment of rhythmic stabilization and TENS. Finally the authors stated that TENS adds no apparent benefit to that of rhythmic stabilization alone.

Study: Shimoji 2006	
Study Design	<ul style="list-style-type: none"> •Random assignment of subjects to 2 groups •Double blinded; specifically patients and operators of devices were blinded •Settings for interventions was a medical institution •Final data analyzed for 21/21 subjects
Characteristics of Participants	<ul style="list-style-type: none"> •Group receiving sham TENS was 64±6 years; group receiving active TENS was 62± 3 years •Group receiving sham TENS experienced CLBP for 2.8 ± 1.1 years; group receiving active TENS experienced CLBP for 2.5±0.9 years •Exclusion criteria: Illnesses or pathologies that would provide a contraindication to electrotherapy such as peripheral vascular abnormalities, peripheral neuropathies, recent trauma and/or menstruation problems; subjects taking antihypertensive drugs or pain relief medications, or were likely to take pain relief medications; inability to attend appointments •It was noted that the diagnoses of the participants were chronic lumbar strain, disc herniation , and spondylosis deformans, with or without osteoarthritis •Subjects who had previously used TENS were allowed to participate in the study as long as they did not express definite beliefs about how TENS worked or whether different types of TENS had different treatment effects
Intervention	<p><u>Treatment groups:</u></p> <ul style="list-style-type: none"> •Massage plus bidirectional modulated sine waves (BMW) TENS; massage plus sham TENS •TENS/sham TENS provided by identical units <p><u>Concurrent Therapy:</u></p> <ul style="list-style-type: none"> •TENS/sham TENS preceded by massage <p><u>Electrical and other parameters of treatment:</u></p> <ul style="list-style-type: none"> •Bidirectional modulated sine wave device producing an amplitude modulated frequency of 122 Hz generated by 4000 -4122Hz wave forms •Mean current amplitude was 17.8 ± 9.4 mA (range 4.5-23 mA) <p><u>Electrode Placement (TENS):</u></p> <ul style="list-style-type: none"> •2 carbon impregnated rubber electrodes (5.5x10 cm) applied to the skin of the back, approximately 10 cm apart from the spine, targeting spinal segments of afferent nerves emerging from the painful area <p><u>Frequency/Duration of treatment sessions:</u></p> <ul style="list-style-type: none"> •Two treatments per week (massage 15 minutes; TENS/sham TENS 15 minutes), with at least a 2 day interval between treatments
Outcome Measures	<ul style="list-style-type: none"> •Numerical rating scale (NRS): 0 = “no pain”, 10 = “worst pain” •Straight leg raising
Timeline of Treatment and Follow up	<ul style="list-style-type: none"> •Treatments were administered for 5 weeks with at least 2 day interval between treatment •Post treatment NSR was collected in week 6 and compared to pretreatment measurement
Adverse Events	<ul style="list-style-type: none"> •Adverse effects did not occur in those subjects receiving BMW TENS
Results	<ul style="list-style-type: none"> •The authors noted that in their patient population, there was no significant difference in outcome measures after treatment with BMW or sham TENS. The authors also concluded that that there were no interactive effects between TENS and massage for treatment of LBP.

Study: Yokoyama 2004

Study Design	<ul style="list-style-type: none">•Random assignment into one of 3 groups•No blinding of patients or physicians•Setting for interventions was a medical institution•Final data analyzed for 53/60 subjects
Characteristics of <u>Participants</u>	<ul style="list-style-type: none">•Ages: group receiving PENS: 60±12 years; group receiving PENS then TENS, 58±14 years; group receiving TENS, 59±13years•LBP for more than 6 months•Inclusion criteria: peak pain intensity of greater than 40 on a visual analog scale (see below); pain intensity had been maintained at stable level for at least 3 months prior to enrollment with non-steroidal anti-inflammatory drugs (NSAIDs) ; no experience with PENS; had received prior treatment with nerve blocks, physical therapy, and NSAIDs•Exclusion criteria: pregnancy, osteomyelitis of the spine, discitis, tumor, ankylosing spondylitis, recent vertebral fracture, structural scoliosis, previous low back surgery
Intervention	<p><u>Treatment groups:</u></p> <ul style="list-style-type: none">•PENS, PENS and TENS, TENS <p><u>Concurrent Therapy:</u></p> <ul style="list-style-type: none">•Allowed to continue NSAIDs as desired•Nerve blocks, physical therapy discontinued at time of study <p><u>Electrical and other parameters of treatment:</u></p> <ul style="list-style-type: none">•PENS therapy: 10, 32 gauge acupuncture like needles were placed 2 - 4 cm deep into the soft tissue/muscle of the low back according to the dermatomal distribution of pain; the needles were connected to bipolar leads from a low output generator (DC current); probes stimulated at 4/30 Hz; intensity of stimulus adjusted to produce the stimulus of the highest tolerable sensation without muscle contraction•TENS therapy: Stimulation occurred at a frequency of 4/30 Hz <p><u>Electrode Placement (TENS):</u></p> <ul style="list-style-type: none">•Stimulation performed by 4 electrodes (2.5 cm) placed in standardized dermatomal pattern <p><u>Frequency/Duration of treatment sessions:</u></p> <ul style="list-style-type: none">•Twice weekly sessions•TENS and PENS stimulation occurred for 20 minutes per session
Outcome Measures	<ul style="list-style-type: none">•Visual analog scale (0-100, with 0 = no pain; 100 = worst pain ever) ; peak pain on assessment day was rated•Physician assessment of patient impairment: 0 = no impairment; 1 = mild, not affecting most activities; 2 = moderate, cannot perform some strenuous activities; 3 = limited, can only participate in light activities; 4 = severely limited•NSAID consumption as determined by number of pills consumed
Timeline of Treatment and Follow up	<ul style="list-style-type: none">•Treatments provided for a total of 8 weeks (16 sessions) for those in the PENS and TENS group; subjects in PENS then TENS group received first 4 weeks of PENS, then 4 weeks of TENS•Assessments made 2 weeks before the initial treatment, just before the initial treatment (baseline), 3 days after week 2, week 4, and week 8 treatments, then at 1 and 2 months after the sessions
Adverse Events	<ul style="list-style-type: none">•None reported
Results	The authors noted that in the group treated with TENS, a significant decrease in pain intensity occurred only at 8 weeks in comparison to baseline scores; there were no significant differences in physical impairment scores throughout study; there were no significant differences in dosages of NSAIDs as compared to baseline throughout study

TABLE 2: Characteristics of Excluded Studies, Systematic Reviews, Meta- analyses

Study	Reason for Exclusion*
Barker 2008	Duration of TENS treatment less than 4 weeks
Bertalanffy 2005	Study of acute low back pain
Bjordal 2003	Study of post – operative pain
Cheing 1999	Duration of TENS treatment less than 4 weeks
DeSanta 2008(a)	Review article
DeSanta 2008(b)	Review article
Fishbain 1996	Mixed sample of musculoskeletal conditions
Ghonaime 1999	Duration of TENS treatment less than 4 weeks
Grant 1999	Imprecise location of back pain

Study	Reason for Exclusion*
Jarzem 2005(b)	Duration of TENS treatment less than 4 weeks
Johnson 2007	Mixed sample of musculoskeletal conditions
Kerns 2002	Review of pain in individuals with multiple sclerosis
Kerr 2003	Study evaluated acupuncture therapy versus non-functioning TENS comparator
Lehmann 1986	Inpatient treatment
Lin 2010	Study evaluated electro-acupuncture, not TENS
Marchand 1993	Included individuals with rheumatic diseases (ankylosing spondylitis, rheumatoid arthritis)
Melzak 1983	Mixed sample of participants with acute and chronic LBP
Moore 1997	Duration of TENS treatment less than 4 weeks
Rakel 2003	Study of postoperative pain
Rakel 2010	Study confined to healthy subjects
Thompson 2008	Intervention consisted of transcutaneous spinal electroanalgesia, not TENS
Thorsteinsson 1977	Mixed sample of musculoskeletal conditions
Topuz 2004	Duration of TENS treatment less than 4 weeks
Tsukayama 2002	Duration of LBP may be less than 3 months
Tulgar 1991(a)	Duration of TENS treatment less than 4 weeks
Tulgar 1991(b)	Mixed sample of musculoskeletal conditions
Warke 2006	Study participants with diagnosis of multiple sclerosis
Yeung 2003	Study of electroacupuncture
Yip 2007	Mixed sample of musculoskeletal conditions
Zambito 2006	Duration of TENS treatment less than 4 weeks
Zambito 2007	Duration of TENS treatment less than 4 weeks

* Multiple reasons for exclusion may exist, but only one listed

TABLE 3: TENS- Bias

	Deyo 1990	Itoh 2009	Jarzem 2005	Kofotolis 2008	Shimoji 2007	Yokoyama 2004
1.Was there a sham TENS comparator to a TENS intervention?	Yes	No	Yes	Yes	Yes	No
2. Were patients blinded to the sham TENS, which would include being told that they may/may not perceive (nor need to) sensation from the device?	Yes	Not Applicable	Yes	Unknown	Yes	Not applicable

3. Was an assessment done to denote adequacy of patient blinding to active versus sham TENS?	Yes	Not Applicable	No	No	No	Not Applicable
4. Were the subjects in all relevant groups naïve to TENS?	Yes	Unknown	Yes	Yes	No	Unknown
5. Were the outcome assessors blinded?	Yes	Unknown	Physical measurements - yes	Unknown	Unknown	Unknown
6. Were the qualifications and expertise of the clinicians who applied the interventions described?	No	ACP=yes TENS=no	No	No	No	No
7. Were the subjects receiving identical co-therapies (including pain medications)?	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
8. Were those seeking compensation/ disability or those presently on disability, excluded from the trial?	Yes	Unknown	Those seeking disability were excluded, but those on disability were not.	Unknown	Unknown	Unknown
9. Is the rationale for all drop outs specified ?	No	Yes	Yes	Yes	Not applicable	Yes
10. Is the rationale for at least some drop outs associated with the symptoms related to CLBP and/or response to assigned treatment?	Yes	Yes	No	Yes	Not applicable	Yes

APPENDIX B

General Methodological Principles of Study Design (Section VI of the Decision Memorandum)

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention’s potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematic assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to that group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is to the extent that differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of that have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e. g. , using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study’s variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in that confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to that the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study’s external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator’s lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention’s potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study’s selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention’s benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology’s benefits and risk of harm to Medicare beneficiaries.

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